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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/934,900	08/22/2001	John R. Booth	BB1476 US NA	8096

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EXAMINER

MCELWAIN, ELIZABETH F

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 07/30/2003

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/934,900

Applicant(s)

BOOTH ET AL.

Examiner

Elizabeth F. McElwain

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 10-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 14 and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-9, 14 and 15, and to SEQ ID NO:1 and sequences encoding SEQ Id NO: 2, in Paper No. 7 is acknowledged.

2. The claims are objected to for reciting non-elected sequences.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-4, 6, 8, 14 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to a nucleic acid sequence encoding a polypeptide having at least 80% identity to SEQ ID NO: 2, and to constructs comprising said sequence and methods of transforming a host cell with said sequence. However, it remains unclear what the particular structural and functional characteristics of the claimed genus of sequences would be. In fact, the specification describes the claimed sequences as "a diverged class of delta-9 stearoyl fatty acid desaturases", stating that these have substantially identical function in plants as those previously characterized, but they play a more important role in regulating

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fatty acid biosynthesis (page 10 of the specification). Yet, there is no description provided of what particular sequences within the genus claimed would confer this functional activity.

See *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed. Cir. 1997), where it states: "The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA . . . Accordingly, the specification does not provide a written description of the invention"

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, one skilled in the art would not have been in possession of the genus claimed at the time this application was filed.

5. Claims 1-9, 14 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to a nucleic acid sequence encoding a polypeptide having at least 80% identity to SEQ ID NO: 2, and to constructs comprising said sequence and methods of transforming a host cell with said sequence. However, the specification describes the claimed sequences as "a diverged class of delta-9 stearoyl fatty acid

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desaturases", stating that these have substantially identical function in plants as those previously characterized, but they play a more important role in regulating fatty acid biosynthesis (page 10 of the specification). In addition, while the specification asserts that use of the claimed sequences as delta-9 stearoyl fatty acid desaturases has been exemplified in Example 10 (pages 44-45), this example does not indicate that any of the sequences used to transform plants was either SEQ ID NO: 1 or a sequence encoding SEQ ID NO: 2. This example states that pDS3 is as good or better than pDS1 at raising stearic acid levels in oil. However, it is unclear what these constructs are and how they relate to the data presented in Table 10 or to SEQ ID NO: 1 and 2.

Therefore, it remains uncertain how one would use SEQ ID NO: 1 or sequences encoding SEQ ID NO: 2, much less any sequences that are at least 80% identical to a sequence encoding SEQ ID NO: 2. Furthermore, the specification fails to provide guidance with regard to evaluating any plants transformed with any of the claimed sequences, and there is no guidance with regard to evaluating the expression of diverged delta-9 stearoyl fatty acid desaturases in host cells or plants.

In addition, sequence homology is not sufficient to predict function of encoded sequences. See the teachings of Doerks (TIG 14, no. 6: 248-250, June 1998), where it states that computer analysis of genome sequences is flawed, and "overpredictions are common because the highest scoring database protein does not necessarily share the same or even similar functions" (the last sentence of the first paragraph of page 248). Doerks also teaches homologs that did not have the same catalytic activity because active site residues were not conserved (page 248, the first sentence of the last paragraph). In addition, Smith et al (Nature Biotechnology 15:1222-1223, November

1997) teach that “there are numerous cases in which proteins of very different functions are homologous” (page 1222, the first sentence of the last paragraph). Also, Brenner (TIG 15, 4:132-133, April 1999) discusses the problem of inferring function from homology, stating that “most homologs must have different molecular and cellular functions” (see the second full paragraph of the second column of page 132, for example). Furthermore, Borks (TIG 12, 10:425-427, October 1996) teaches numerous problems with the sequence databases that can result in the misinterpretation of sequence data.

More specifically, identification of related sequences that will encode enzymes having a particular activity is particularly problematic in the enzymes involved in modifying fatty acids, and cannot be determined merely by similarity of DNA or amino acid sequences. Van de Loo et al teach that sequences encoding fatty acid hydroxylase activity are highly similar to other sequences that do not encode a hydroxylase, but instead encode a fatty acyl desaturase (see the abstract, at least). In fact, Broun et al teach that a change in only four amino acids will convert a desaturase gene to a hydroxylase gene (see the abstract, at least). Thus, if sequences are identified only by similarity to other sequences that are known to encode fatty acid desaturases, one cannot conclude that these other sequences also encode enzymes having fatty acid desaturase activity. In addition, De Luca teaches that modifying plant biosynthetic pathways by transforming plants with genes encoding enzymes involved in said pathway is highly unpredictable (see the paragraph bridging the columns on page 225N, for example), and that “on many occasions desired goals have been impossible to achieve” (see the last paragraph on page 228N). Therefore, both the identification of

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other genes encoding diverged delta-9 fatty acid desaturase activity, and the modification of plant lipid composition by transforming a plant with said gene or a portion of said gene are highly unpredictable.

Thus, given the unpredictability of identifying sequences that exhibit fatty acid desaturase activity and modifying the lipid composition of a plant or cell; the lack of guidance in the specification for identifying and characterizing sequences that exhibit fatty acid desaturase activity; the lack of working examples of fatty acid desaturase activity coding sequences, and the lack of working examples of similar sequences that encode proteins having the same activity; and the breadth of the claims, which encompass a multitude of sequences and use of a wide variety of host cells to modify a fatty acid; it would require undue experimentation by one skilled in the art to make and use the invention as broadly claimed.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-3, 6 and 8 are rejected under 35 U.S.C. 102(a) as being anticipated by Swiderski et al (Plant Science 151:75-83, 2000 in IDS, see alignment with sequence Accession AF139377, March 17, 2000).

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The claims are drawn to a nucleic acid sequence encoding a polypeptide having at least 80% identity to SEQ ID NO: 2, and to constructs comprising said sequence and host cells transformed with said sequence.

Swiderski et al teach a nucleic acid sequence encoding a polypeptide having at least 90% identity to SEQ ID NO: 2, and said clone in a cDNA library which would require the sequence in a construct and a host cell.

8. Claims 1 and rejected under 35 U.S.C. 102(b) as being anticipated by Sato et al (Plant Physiol. 99:362-363, 1992). *Accession M83199.*

Sato et al teach a nucleic acid sequence encoding a polypeptide having at least 80% identity to SEQ ID NO: 2, and said clone in a cDNA library which would require the sequence in a construct and a host cell.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is 703-308-1794. The examiner can normally be reached on increased flex time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Elizabeth F. McElwain, Ph.D.
Primary Examiner
Art Unit 1638

EFM
July 29, 2003